

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>In re Application of</p> <p>Mark S. Dennis</p> <p>Serial No.: To be assigned</p> <p>Filed: August 11, 2003</p> <p>For: FVIIa Antagonists</p>	<p>Group Art Unit: To be assigned</p> <p>Examiner: To be assigned</p> <p>Confirmation No: To be assigned</p> <p>CUSTOMER NO: 09157</p> <hr/> <p>Express Mail No. EV 351927891 US Mailed August 11, 2003</p>
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicant submits herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

(X) **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

0 **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set

forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/632,429, filed August 4, 2000 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) (Required)

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: August 11, 2003

By: 

Jeffrey S. Kubinec

Reg. No. 36,575

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FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)	U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P1639R1C1	Serial No.
		Applicant Mark S. Dennis	
		Filing Date 11 Aug 2003	Group

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	5,116,964	26.05.92	Capon et al.			
	* 2	5,336,603	09.08.94	Capon et al.			
	* 3	5,583,111	10.12.96	Hemberger et al.			
	* 4	5,714,147	03.02.98	Capon et al.			
	* 5	5,759,954	02.06.98	Taguchi et al.			
	* 6	5,834,244	10.11.98	Dennis et al.			
	* 7	5,863,893	26.01.99	Dennis et al.			
	* 8	5,880,256	09.03.99	Dennis et al.			
	* 9	6,087,487	11.07.00	Vlasuk et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	*10	WO 00/04148	27.01.00	PCT			
	*11	WO 90/03390	05.04.90	PCT			
	*12	WO 91/11514	08.08.91	PCT			
	*13	WO 95/00541	05.01.95	PCT			
	*14	WO 96/40779	19.12.96	PCT			
	*15	WO 97/20939	12.06.97	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	*16	Badimon et al., "Hirudin and Other Thrombin Inhibitors: Experimental Results and Potential Clinical Applications" <u>Trends Cardiovasc. Med.</u> 1(6):261-267 (1991)
	*17	Banner et al., "The crystal structure of the complex of blood coagulation factor VIIa with soluble tissue factor" <u>Nature</u> 380:41-46 (1996)
	*18	Bone, R. C., "Modulators of Coagulation: A Critical Appraisal of Their Role In Sepsis" <u>Arch Intern Med</u> 152:1381-1389 (1992)
	*19	Capon et al., "Designing CD4 Immuno adhesins for AIDS Therapy" <u>Nature</u> 337:525-531 (1989)
	*20	Carson and Brozna, "The role of tissue factor in the production of thrombin" <u>Blood. Coag. Fibrinol</u> 4:281-292 (1993)
	*21	Clackson and Wells, "In Vitro Selection from Protein and Peptide Libraries." <u>Trends Biotechnol.</u> 12:173-184 (1994)
	*22	Colman, R. W., "The Role of Plasma Proteases In Septic Shock" <u>The New England J. of Med.</u> 320(18):1207-1209 (1989)
	*23	Creasey et al., "Tissue Factor Pathway Inhibitor Reduces Mortality from Escherichia coli Septic Shock" <u>J. Clin. Invest.</u> 91:2850-2860 (1993)
	*24	Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis" <u>Science</u> 244:1081-1085 (1989)

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*25	Cwirla et al., "Peptides on phage: a vast library of peptides for identifying ligands" <u>Proc. Natl. Acad. Sci. USA</u> 87(16):6378-6382 (1990)				
*26	Davie et al., "The Coagulation Cascade: Initiation, Maintenance, and Regulation" <u>Biochemistry</u> 30(43):10363-10370 (1991)				
*27	Dennis and Lazarus, "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa; I. Potent Inhibitors Selected from Libraries by Phage Display" <u>Journal of Biological Chemistry</u> 269(35):22129-22136 (1994)				
*28	Dennis and Lazarus, "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa; II. Potent and Specific Inhibitors by Competitive Phage Selection" <u>Journal of Biological Chemistry</u> 269(35):22137-22144 (1994)				
*29	Dennis et al., "Binding interactions of kistrin with platelet glycoprotein IIb-IIIa: analysis by site-directed mutagenesis" <u>Proteins: Structure, Function, and Genetics</u> 15(3):312-321 (1993)				
*30	Dennis et al., "Peptide Exosite Inhibitors of Factor VIIa as Anticoagulants." <u>Nature</u> 404:465-470 (Mar 2000)				
*31	Dickinson et al., "Influence of Cofactor Binding and Active Site Occupancy on the Conformation of the Macromolecular Substrate Exosite of Factor VIIa" <u>J. Mol. Biol.</u> 277:959-971 (1998)				
*32	Hagen et al., "Characterization of a cDNA coding for human factor VII" <u>Proc. Natl. Acad. Sci. USA</u> 83:2412-2416 (1986)				
*33	Harlos et al., "Crystal structure of the extracellular region of human tissue factor" <u>Nature</u> 370:662-666 (1994)				
*34	Haskel et al., "Prevention of Arterial Reocclusion After Thrombolysis With Recombinant Lipoprotein-Associated Coagulation Inhibitor" <u>Circulation</u> 84(2):821-827 (1991)				
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*36	Holst et al., "Antithrombotic Properties of a Truncated Recombinant Tissue Factor Pathway Inhibitor in an Experimental Venous Thrombosis Model" <u>Haemostasis</u> 23(Suppl. 1):112-117 (1993)				
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*38	Kelly et al., "Ca ²⁺ Binding to the First Epidermal Growth Factor Module Coagulation Factor VIIa Is Important for Cofactor Interaction and Proteolytic Function" <u>Journal of Biological Chemistry</u> 272:17467-17472 (1997)				
*39	Lee et al., "Potent Bifunctional Anticoagulants: Kunitz Domain-Tissue Factor Fusion Proteins" <u>Biochemistry</u> 36(19):5607-5611 (1997)				
*40	Lowman et al., "Molecular Mimics of Insulin-Like Growth Factor 1 (IGF-1) for Inhibiting IGF-1: IGF-Binding Protein Interactions." <u>Biochemistry</u> 37(25):8870-8878 (1998)				
*41	Lowman et al., "Selecting High-Affinity Binding Proteins by Monovalent Phage Display" <u>Biochemistry</u> 30(45):10832-10838 (1991)				
*42	Lowman, H., "Bacteriophage display and discovery of peptide leads for drug development" <u>Annual Review of Biophysics and Biomolecular Structure</u> 26:401-424 (1997)				
*43	Muller et al., "Structure of the Extracellular Domain of Human Tissue Factor: Location of the Factor VIIa Binding Site" <u>Biochemistry</u> 33(36):10864-10870 (1994)				
*44	O'Brien et al., "Factor VIII-Bypassing Activity of Bovine Tissue Factor Using the Canine Hemophilic Model" <u>J. Clin. Invest.</u> 82:206-211 (1988)				
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	*45	Orning et al., "A peptide sequence from the EBF-2 like domain of FVII inhibits TF-dependent FX activation" <u>Thrombosis Research</u> 86(1):57-67 (1997)			
	*46	Paborsky et al., "Lipid Association, but Not the Transmembrane Domain, Is Required for Tissue Factor Activity" <u>Journal of Biological Chemistry</u> 266:21911-21916 (1991)			
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	*48	Roy et al., "Self-association of Tissue Factor as Revealed by Chemical Cross-linking" <u>Journal of Biological Chemistry</u> 266(8):4665-4668 (1991)			
	*49	Scott and Smith, "Searching for peptide ligands with an epitope library" <u>Science</u> 249:386-390 (1990)			
	*50	Smith, G. P., "Surface presentation of protein epitopes using bacteriophage expression systems" <u>Curr. Opin. Biotechnol.</u> 2(5):668-673 (1991)			
	*51	Wells and Lowman, "Rapid evolution of peptide and protein binding properties in vitro" <u>Curr. Opin. Biotechnol.</u> 3:355-362 (1992)			
	*52	Wildgoose et al., "Identification of a Calcium Binding Site in the Protease Domain of Human Blood Coagulation Factor VII: Evidence for Its Role in Factor VII-Tissue Factor Interaction" <u>Biochemistry</u> 32:114-119 (1993)			
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